REMARKS

Applicants have amended independent claims 1 and 23 to delete terms to overcome rejections to new matter and indefiniteness. For all these reasons, the amendments to the claims do not add new matter.

Summary of Bases for Objection/Rejection

Claims 1, 3-23, 31 and 37 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement.

Claims 1, 3-22, 31 and 37 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

Claims 1, 3-6, 19-20, 22-23, 31 and 37 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Zhang et al., *A Quantitative Assesment of Osteoinductivity of Human Demineralized Bone Matrix*, Journal of Periodontology, Vol. 68(11), pp. 1076-1084 (Nov. 1997).

The Applicant will address each of the above bases of rejection in sections I - III, respectively, which follow.

I. 35 U.S.C. §112, First Paragraph (Written Description)

Claims 1, 3-23, 31 and 37 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. As its first basis for rejection, the Patent Office contends that the Applicants' use of "TGF" in the claims as an acronym for "tissue growth factor" constitutes new matter because the abbreviation is used in the specification as an acronym got another compound "transformation growth factor." To avoid any confusion, the Applicants have amended claims 1 and 23 to delete the acronym "TGF." Accordingly, this basis for rejecting independent claims 1 and 23, and their respective dependents (claims 3-22, 31 and 37) has been rendered moot.

II. 35 U.S.C. §112, Second Paragraph

Claims 1, 3-22, 31 and 37 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. In particular, claim 1 is rejected in its recitation at line 5 of "like implant materials comprising bone." [Official Action at page 3.] Applicants previously deleted "like" in line 2 but missed the second recitation of "like" in line 5. In response, the applicants have amended claim 1 to delete "like" in line 5. Accordingly, this basis for rejection has been rendered moot.

III. 35 U.S.C. §102(b) over Zhang

Claims 1, 3-6, 19-20, 22-23, 31 and 37 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Zhang *et al.*, *A Quantitative Assesment of Osteoinductivity of Human Demineralized Bone Matrix*, Journal of Periodontology, Vol. 68(11), pp. 1076-1084 (Nov. 1997). The Examiner alleges that "Zhang et al. disclose an *in vitro* method for quantifying the osteoinductive potential of demineralized bone matrix (DBM), which is a collection of implant material containing bone morphogenic proteins (BMP's) and other noncollagenous proteins, from cadaverous humans before clinical (human) use (allograft) . . . as cited in claims 1 and 23." [Official Action at page 4, citing to Zhang at the title, abstract, and page 1077, col. 2, 2nd and 3rd paragraphs.] While the in vitro assays of Zhang are *in vitro* in so far as they are performed in a test tube, they all require living cells. See Zhang at page 1078, col. 1. In contrast, the method of the Applicants invention as recited in independent claims 1 and 23 specifically states that it "does not use a living biological entity." For this reason alone, claims 1 and 23, and their dependents (claims 3-6, 19-20, 22, 31 and 37), would not be anticipated by Zhang. Because Zhang's *in vitro* assay requires the use of cells, Applicants' *in vitro* assay, which does not require the use of cells, would not have been obvious over Zhang at the time that the Applicants' invention was made.

Separately, each of independent claims 1 and 23 recites as an element "osteogenic factor is selected from the group consisting of a bone morphogenetic protein (BMP), a tissue growth factor ~~(TGF)~~, a fibroblast growth factor (FGF), a platelet derived

growth factor (PDGF), a vascular endothelial growth factor (VEGF), a cartilage derived morphogenetic proteins, an insulin-like growth factor (IGF) and a combination thereof. . . ." None of the analytes is "alkaline phosphatase" (ALP). In contrast, the only "in vitro" assay (albeit with cells) disclosed in Zhang is for the protein alkaline phosphatase. See Zhang at page 1078, cols. 1-2. For this reason also, claims 1 and 23, and their dependents (claims 3-6, 19-20, 22, 31 and 37), would not be anticipated by Zhang.

Moreover, there is no evidence that alkaline phosphatase is an art recognized equivalent of any of the growth factors of the Applicants' Markush group. According to Zhang, alkaline phosphatase is "an indicator of osteoblast induction." [Zhang at the Abstract.] Zhang never associates alkaline phosphatase with any specific member of the Applicants Markush group. In fact, Zhang demonstrates that there is no linear relationship between alkaline phosphatase activity and any growth factor in the DBM. In particular, one skilled in the art (or even a high school science student) recognizes that for any batch of DBM, the amount of DBM is proportional to the amount of its growth factor component. Hence, doubling the amount of DBM would double the amount of the growth factor provided. Providing 10x the amount of DBM should provide 10X the amount of growth factor. If alkaline phosphatase activity were proportional to the amount of growth factor in the DBM (and thus proportional to amount of DBM), then 10x the amount of DBM should give 10x the amount of alkaline phosphatase activity. However, in Figure 7 of Zhang, Zhang discloses that 20 mg of DBM produces about 2/3 the alkaline phosphatase activity of 2 mg of DBM. More significantly, Figure 7 discloses that 2 mg of DBM produces twice the alkaline phosphatase activity as 20x more (40 mg) of DBM and thus, twice the alkaline phosphatase activity as 20x more of growth factor. Consistent with this lack of any relationship between alkaline phosphatase activity and the amount of DBM, and thus the amount of growth factor, Zhang teaches that "Cultures receiving 2 mg, 20, mg, 30 mg, and 40 mg of DBM exhibited **significantly less ALP** activity as compared to cultures receiving 5 and 10 mg of DBM (Fig. 7)." [Zhang at p. 1082, col. 1; emphasis added in bold.]

For all these reasons, the different method of claims 1 and 23 and their dependents (claims 3-6, 19-20, 22, 31 and 37) is neither anticipated by nor obvious over Zhang.

SUMMARY

Claims 1, 3-23, 31 and 37 stand rejected. In view of the amendments and arguments provided herein, the rejection of claims 1, 3-23, 31 and 37 under 35 U.S.C. §112, first paragraph, for failure to satisfy the written description requirement have been rendered moot. In view of the amendments and arguments provided herein, all bases for rejecting claims 1 and 3-22, 31 and 37 under 35 U.S.C. §112, second paragraph, for indefiniteness have been rendered moot. In view of the arguments and evidence provided herein, all bases for rejecting claims 1, 3-6, 19-20, 22-23, 31 and 37 under 35 U.S.C. §102(b) over Zhang have been rendered moot and/or rebutted.

For all these reasons, claims 1, 3-23, 31 and 37 are in condition for allowance. The allowance of claims 1, 3-23, 31 and 37 is respectfully requested.

Respectfully submitted,

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